DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 13, 2014

Zimmer, Inc.
Stephen H. McKelvey, MA, RAC
Senior Project Manager, Trauma Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K141517
Trade/Device Name: Zimmer® Plates and Screws System (ZPS) – Non-Sterile Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: June 18, 2014
Received: June 19, 2014

Dear Mr. Stephen H. McKelvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141517

Device Name
Zimmer Plates and Screws System (ZPS) - Non-Sterile Plates

Indications for Use *(Describe)*

ZPS Plates are indicated for temporary internal fixation and stabilization of osteotomies and fractures. Smaller-sized ZPS plates are used for small bones and small fragments of the hands and feet. ZPS Calcaneal plates are indicated for temporary internal fixation and stabilization of osteotomies and fractures of the calcaneus. ZPS Screws are temporary internal fixation devices designed to stabilize fractures during the normal healing process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

510(k) Summary

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Stephen H. McKelvey Senior Project Manager, Trauma Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 371-8760
Date:	June 6, 2014
Trade Name:	*Zimmer*® Plates and Screws System (ZPS) – Non-Sterile Plates
Common Name:	Temporary Internal Fixation Devices
Classification Names and References:	Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)
Classification Panel:	Orthopedics/87, Product code HRS
Predicate Device(s):	TMP Micro-plating System (Anspach/Techmedica, K921458, cleared July 17, 1992) and Synthes Calcaneal Plate (K020401, cleared May 8, 2002).
Purpose and Device Description:	The Zimmer Plates and Screws System (ZPS) is a non-locking, stainless steel plate and screw system. Plate shapes vary to address varying patient bone sizes and injury fragment sizes. Plates incorporate a spherical sliding slope plate hole design to achieve the compression required to treat bone fractures. The plates are used with ZPS screws for temporary fixation to the bone.
Intended Use:	ZPS Plates are indicated for temporary internal fixation and stabilization of osteotomies and fractures. Smaller-sized ZPS plates are used for small bones and small fragments of the hands and feet. ZPS Calcaneal plates are indicated for temporary internal fixation and stabilization

of osteotomies and fractures of the calcaneus. ZPS Screws are temporary internal fixation devices designed to stabilize fractures during the normal healing process.

Comparison to Predicate Device: The ZPS plates are similar in intended use, basic shape, compatible screw hole diameters, materials and performance characteristics to the predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

- Biocompatibility - Biocompatibility testing on the plate and screw material was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR § 58). All testing passed.

- Beam bending cross sectional analysis was conducted on the subject ZPS plates and compared to their respective predicate devices in order to estimate the static and fatigue bending strength. The ZPS plates were grouped based upon their cross-sectional properties.

  After determining the lowest section modulus (from the cross sectional analysis), the weakest (worst-case) ZPS plate within each of the groups was selected as the representative sample for comparison. The representative ZPS plate sample static and fatigue bending moment calculations were then compared to their respective predicate plate calculations to determine which had the greater bending strength. All calculations used the weakest cross section location of the evaluated plate.

  In all cases, the subject ZPS plates demonstrated higher static and fatigue bending moments (and greater bending strength) than their respective predicate plates. Each of the evaluated subject ZPS plates met their acceptance criteria for this analysis.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for these devices.